

Informed Consent

To help you make an informed decision whether or not to participate in a [clinical trial](#), you must discuss, read, understand, and sign an informed consent form.

If English is not your first language, a translator may be used. It is very important to understand what is involved in a clinical trial.

Informed consent is a process of reading a consent form, talking about the details of the trial, and asking questions. This allows you to make an informed decision about taking part. Participating in a clinical trial is always voluntary and you are able to stop participating at any point in time for any reason.

The informed consent form contains all the information about the trial known to date. The informed consent process allows you to learn:

- Why the trial is being done
- The background information and purpose of the trial
- Who the Sponsor is
- The Principal Investigator
- Contact information
- How long the trial is expected to last
- How many patients are needed to participate
- The possible risks and benefits
- Your legal rights
- Detailed information about what you can expect, such as:
 - Screening processes to determine eligibility
 - Required tests and procedures
 - Details about the treatment or intervention
 - How often you have to come in for appointments
 - Possible side effects
 - Costs
 - Follow-up after the treatment is stopped or the intervention has occurred
- What information is collected about you
- How your [privacy is protected](#)
- When and how you will receive updated information about the trial

By signing the informed consent form, you indicate that you understand all of the information given. You are aware you can change your mind at any time for any reason. A copy of the signed consent form is given to you to keep. Once you sign the informed consent form, [screening](#) will take place to see if you are eligible for the trial.

Informed consent is an ongoing process. You are encouraged to ask questions and you will be told whenever new information about the clinical trial is known.